

43. (Amended) A diagnostic comprising one or more oligonucleotides according to claim 26.

44. (Amended) A test kit comprising one or more oligonucleotides according to claim 26.

REMARKS

With entry of this Amendment, claims 26-35 AND 41-44 are pending in the application. Applicants have amended claim 26 to make it independent. Claims 27, 35, and 41-44 have been amended to correct their dependency. These amendments do not introduce new matter.

Applicants acknowledge withdrawal of the rejections under section 102(b) over references by Evans and Sommergruber. Office action, page 2.

I. Rejections Under 35 U.S.C. § 112, First Paragraph

A. The Specification Describes the Claimed Invention

Claims 24-44 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking adequate written description. Office action, page 2. Applicants traverse the rejection, which is moot as to canceled claims 24, 25, and 36-40.

Applicants traverse because all of the pending claims are directed to particular species of oligonucleotides that are fully described in the specification as filed. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

B. The Specification Enables the Full Scope of the Claims

The Office has maintained the rejection of claims 24-44 under 35 U.S.C. § 112, first paragraph, because the specification, while admittedly enabling for "in vitro inhibition of expression of nucleic acids encoding human tenascin of SEQ ID NO: 1 by

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the antisense [oligonucleotides] claimed" allegedly does not enable their use *in vivo*. Office action, page 3. Applicants traverse the rejection for the reasons of record, supplemented as follows.

The Office admits that the specification fully enables use of the claimed oligonucleotides *in vitro*, and no assertion that one of ordinary skill in the art could not make the oligonucleotides without undue experimentation has been made. The claims are not limited to a particular use for the invention, specifically, use *in vivo*. "[W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use." M.P.E.P. § 2164.01(c). Since the Office has admitted that the claimed oligonucleotides are enabled for *in vitro* uses, this rejection is improper. Applicants respectfully request that the Office reconsider and withdraw it.

II. The Claims Are Patentable Over the Prior Art

Claims 24-35 and 42 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Denner, Cleek (I), and Cleek (II) in view of Baracchini and Friesen. Office action, page 4. Applicants traverse the rejection for the reasons of record, supplemented as follows.

Applicants submit that the claims are not *prima facie* obvious over this combination of references because the references fail to teach or suggest all of the limitations of the claims. The claims recite particular species of oligonucleotides. In certain of the dependent claims, such as claims 32-34, these particular species possess specific modifications. The primary references do not teach these recited features of

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the claims. The Office does not dispute this. Office action mailed April 24, 2001, page 12; "The primary references do not teach antisense oligonucleotides between 7 and 17 nucleotides in length and including SEQ ID Nos: 2-20, which target and inhibit tenascin expression, nor do they teach all of the nucleobase and sugar modifications set forth in the claims including 3'-3' or 5'-5' inversions."

Combining the secondary references with the primary references does not cure this deficiency because the secondary references do not teach or suggest the species of oligonucleotides recited in the claims, nor do they teach or suggest the specific modifications. These references merely provide a general teaching of various chemical modifications one can make to antisense oligonucleotides. A general incentive in the art, however, does not render obvious Applicants' specific invention. *Cf. In re Deuel*, 34 U.S.P.Q.2d 1210, 1216 (Fed. Cir. 1995). That is, a general incentive to modify the oligonucleotides of the primary references is not a teaching or suggestion of the specific oligonucleotides recited in the claims.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Conversely, the Office may not ignore limitations in a claim to find the claim unpatentable over the prior art. Because the cited references do not teach or suggest all of the limitations of the claims, the Office has not established a *prima facie* case of obviousness. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

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CONCLUSION

In view of these amendments and remarks, Applicants submit that this application is in condition for allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Appendix

26. (Amended) [The] An oligonucleotide [according to claim 24,] comprising a sequence

selected from[the group consisting of]:

SEQ. ID NO. 2: 3'- GGT TTGGGTGGAGGTGG -5',
SEQ. ID NO. 3: 3'- GGAGGTGGTACCCCCCGG -5',
SEQ. ID NO. 4: 3'- GGTGGTACCCCCCGG -5',
SEQ. ID NO. 5: 3'- GGAGGTGGTACCCC -5',
SEQ. ID NO. 6: 3'-AGAAAGAACGAAAGGAA -5',
SEQ. ID NO. 7: 3'- GGAGGTGGTACC -5',
SEQ. ID NO. 8: 3'- GGAGCGATGGCTTCCA -5',
SEQ. ID NO. 9: 3'- AAAGGAACGGGAGCG -5',
SEQ. ID NO. 10: 3'- GGT CGGTTTGGGTGG -5',
SEQ. ID NO. 11: 3'- CTTACAGGTCCGTTGA -5',
SEQ. ID NO. 12: 3'- GGCCGTGTTGCTGT -5',
SEQ. ID NO. 13: 3'- TCACCCCTCTTCTGG -5',
SEQ. ID NO. 14: 3'- GGACACCGACACGG -5',
SEQ. ID NO. 15: 3'-AACGGGAGCGATGG-5',
SEQ. ID NO. 16: 3'- ATCTCGGGGTCGTC -5',
SEQ. ID NO. 17: 3'-AAAGAACGAAAGGAA-5',
[SEQ. ID NO. 18: 3'- GGTGGTACCCC -5',]
SEQ. ID NO. 19: 3'- CCCGGTACTGA -5', [and] or
SEQ. ID NO. 20: 3'- CCACAGAAAGAAC -5'.

27. (Amended) An oligonucleotide according to [any one of claims 24, 25, or] claim 26, wherein the oligonucleotide has one or more modifications.

35. (Amended) The method for inhibiting the expression of tenascin by administering an oligonucleotide according to [any one of claim 24-26] claim 26.

41. (Amended) A process for the production of a pharmaceutical[,]
comprising mixing [wherein] an efficacious dose of one or more oligonucleotides according to claim 26 [any one of claims 24-26 is mixed] with one or more pharmaceutical vehicles and/or additives.

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42. (Amended) A process for the preparation of an oligonucleotide according to claim 26 [one of claims 24-26], the oligonucleotide being chemically synthesized on a solid phase.

43. (Amended) A diagnostic comprising one or more oligonucleotides according to claim 26 [any one of claims 24-26].

44. (Amended) A test kit comprising one or more oligonucleotides according to claim 26 [any one of claims 24-26].

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